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(54) Peritoneal dialysis equipment

(57) In peritoneal dialysis equipment a removable connection is formed between the catheter 1 and the giving tube 3 within a temporary clean enclosure formed by a flexible wall 11. Preferably the catheter 1 and the giving tube 3 each end at a boss 9, 12 and the flexible wall 11 takes the form of a tube of bellows construction attached permanently around one boss and fitting tightly over the other. A plug 16 may be provided within the enclosure for sealing the catheter 1 when it is not connected to the giving tube 3, and a peg 15 may be provided on the boss 12 of the giving tube 3 for supporting the plug 16 when not in use.

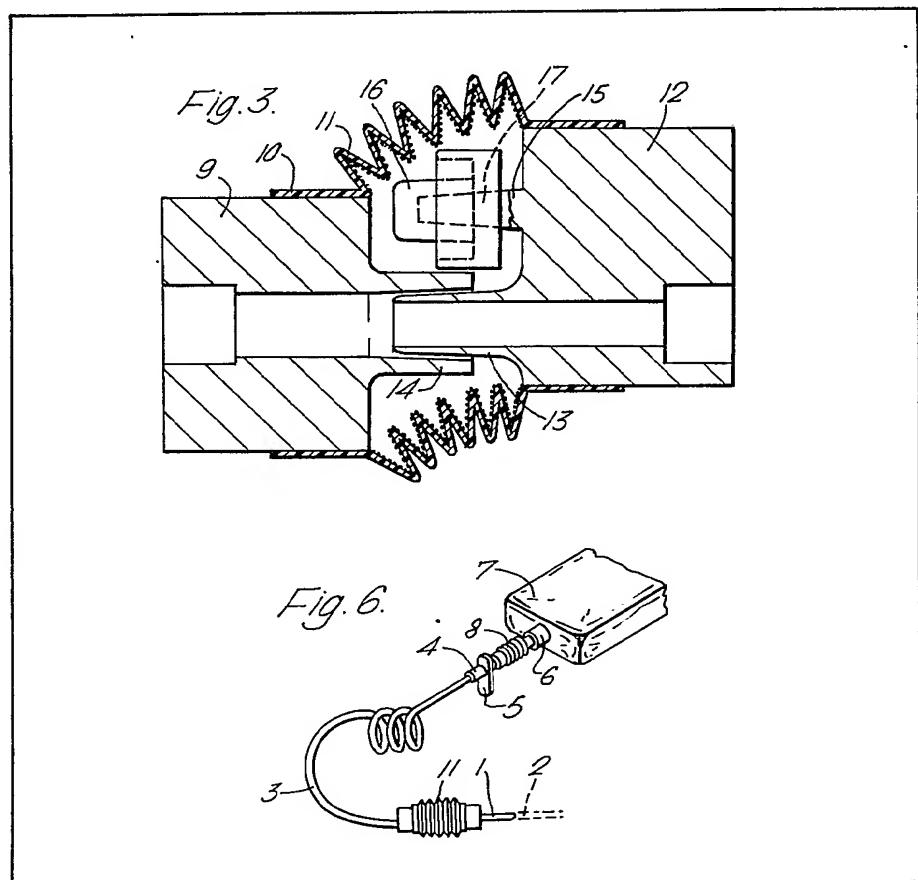


Fig. 1.

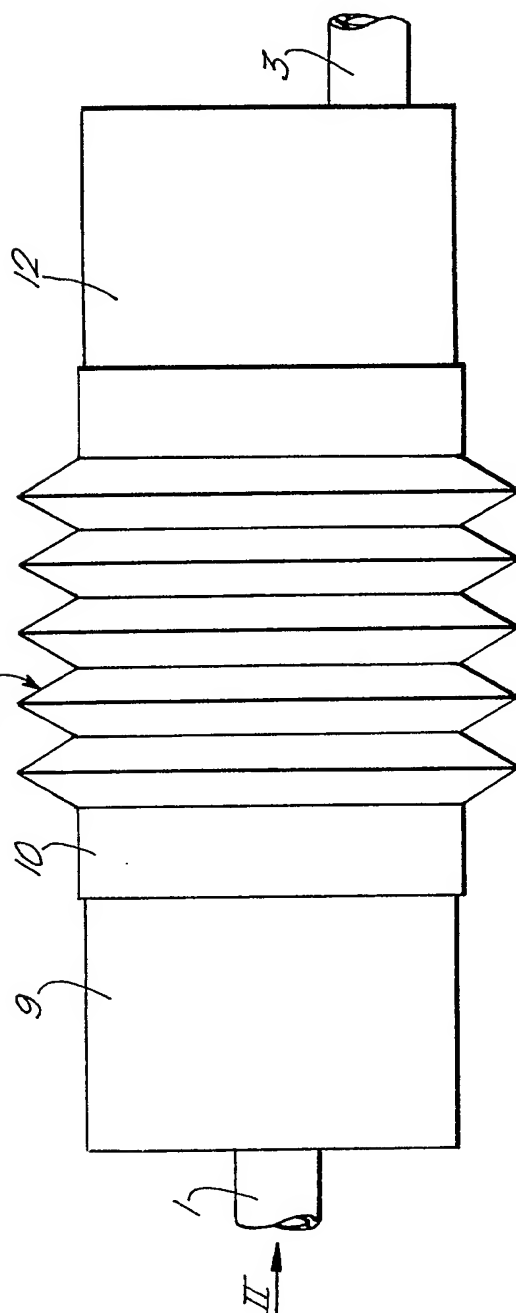
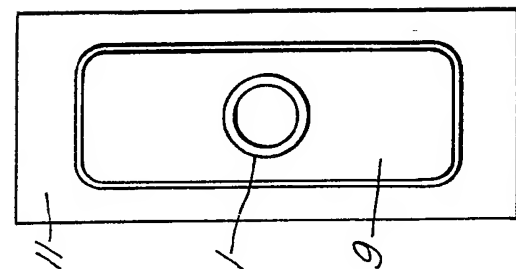


Fig. 2.

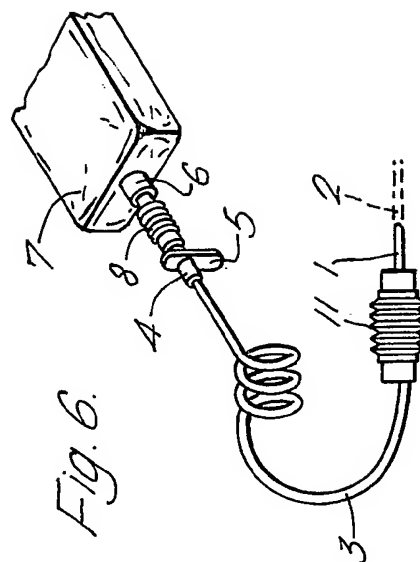


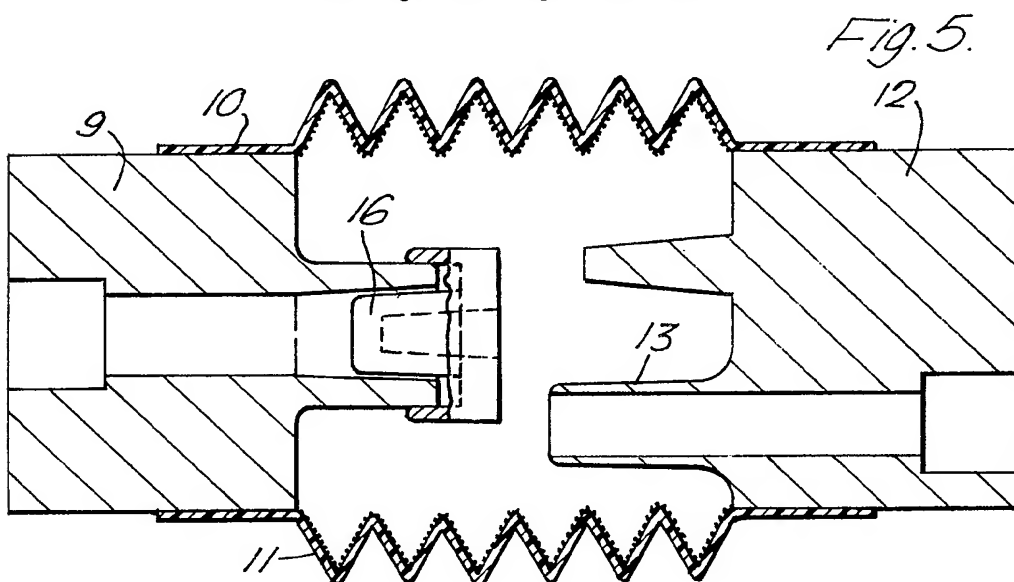
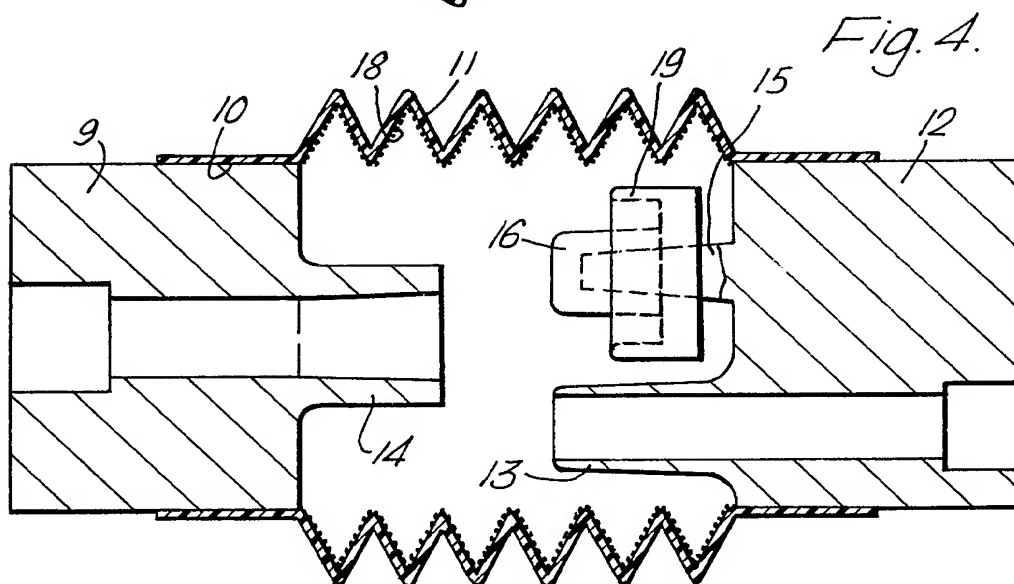
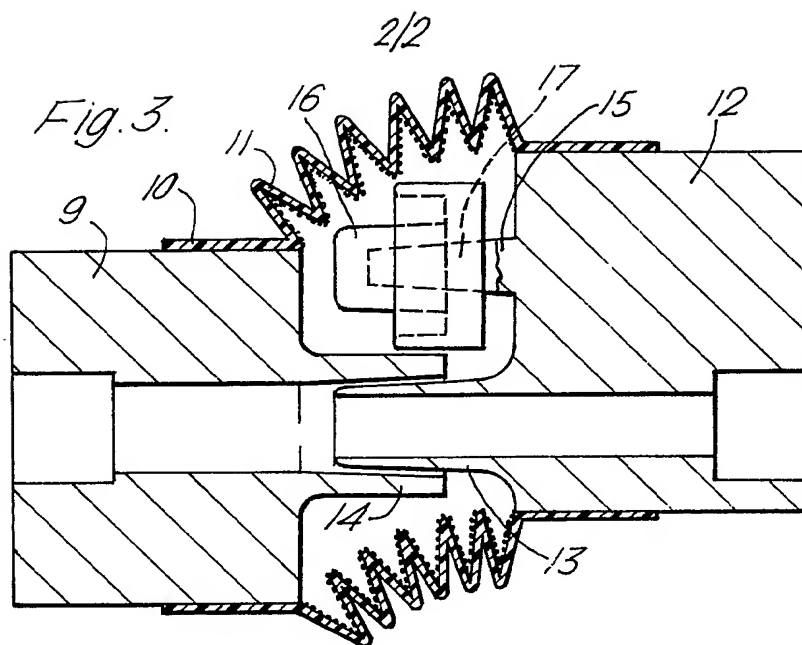
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Fig. 6.





SPECIFICATION

Peritoneal dialysis equipment

5 This invention relates to the equipment used in peritoneal dialysis and is concerned with the connectors which are used in that equipment.

For peritoneal dialysis an incision is made in the abdominal wall and a catheter is inserted semi-permanently through it so that its inner end is within the enclosure formed by the peritoneal membrane. The catheter projects outside the abdominal wall and there is connected to a long flexible tube which is known as the giving tube.

15 The treatment consists in applying through the giving tube from a sterile bag a quantity, which varies according to the patient but is usually between one and two litres, of a carefully formulated and sterilised fluid. This perfuses the region within the peritoneal membrane and there is osmosis through the peritoneal membrane. After a given period which will depend on the precise nature of the treatment the fluid is withdrawn through the catheter and the giving tube and disposed of, and a fresh quantity of fluid is fed in.

The exact nature of the treatment will depend on whether the treatment is being performed in a hospital or other special centre (in which case the fluids are being inserted and withdrawn mechanically by machine while the patient remains inactive) or whether it is a process known as continuous ambulatory peritoneal dialysis (CAPD) where the patient himself connects the filled bag and after the treatment drains the liquid as necessary. The latter is of course a preferable treatment from the point of view of the mobility of the patient, of the low equipment and overhead costs and of the fact that no skilled medical staff are necessary.

However both these procedures depend on the connection and disconnection of the catheter and/or the giving tube to the fluid bags involved or the machine involved.

The abdominal cavity within the peritoneal membrane is particularly susceptible to infection and it is of the utmost importance that sterility should be preserved in these connections. Although this is less of a problem in the hospital where skilled staff are available the difficulties and dangers facing the patient undergoing a CAPD regime are obvious.

50 Occasionally it is necessary to change the connection between the catheter and the giving tube. Furthermore a modification of construction could be envisaged in which the giving tube was an integral part of the bag and then the sole connection to be made would be between the catheter and that tube. The catheter by its nature cannot be provided with a spike nor reasonably could one expect the giving tube to be provided with a spike on the end which fits to the catheter since the patient would run a risk of impaling himself. The fitting of the giving tube to the catheter is an intricate procedure since there is a short projection of the latter, and the present invention is concerned to improve and make easier and safer the making of such a connection to which of course apply all the considerations concerning steril-

ity which have been mentioned above.

The present invention provides means whereby there is established around the boss end of the catheter a temporary and clean enclosure within which connection and plugging operations can be carried out on the end of the catheter. The enclosure is defined by a flexible wall. It is flexible both in the axial direction and in the transverse direction (that is to say transverse to the axis of the catheter and tube). This temporary enclosure includes the end of the giving tube which is to fit to the catheter and also a temporary retainer for a plug which is also fittable into the end of the catheter. The enclosure is preferably formed by a bellows one end of which is free to fit over the boss end of the catheter and other of which is permanently fixed to a boss end containing the end of the giving tube and the temporary retainer of the plug.

The end of the catheter and the end of the giving tube form a conventional male/female Luer locking taper, and the plug is such as to sealingly fit the end of the catheter whether that is male or female.

When as is at the moment conventional the catheter end is the female end the plug includes a central taper-lock male element and preferably also a skirt around the outside which will cover the projecting outer surface of the female catheter end.

Preferred temporary retaining means for the plug is a peg projecting in the axial direction from the boss on the end of the giving tube, parallel to the Luer fitting of the giving tube and forming a force fit within an appropriately dimensioned recess in the centre of the plug.

The temporary enclosure formed by the bellows or other flexible wall preferably includes also a sterilising means which may take the form of a gauze or other absorbent material on the inner surface of the flexible wall and suitably being formed there during the manufacturing process of the material of the wall. This absorbent material is impregnated with a sterilising agent such as Hibitane (R T M).

To change the connection between a giving tube and catheter the taper parts are withdrawn one from the other while the enclosure remains intact. By flexion of the wall of the container the plug held on the temporary retainer is then aligned with and inserted into the end of the catheter. The end of the giving tube is then withdrawn together with the flexible wall leaving a plugged but now exposed end of the catheter. The end of the new giving tube is fitted with a flexible wall for forming the next temporary enclosure. The free end of this is brought over the boss forming the end of the catheter to form a new enclosure, the interior of which will be held clean while the unplugging and connection operation is carried out. If the interior of the flexible wall is impregnated with a sterilising agent the wall may be pressed transversely and flexed by finger pressure to wipe the Luer fitting or fittings. The plug is then withdrawn from the catheter end, preferably by transverse compression of the wall so that it is gripped by the fingers of the user through the wall, and is placed on the temporary retaining means. Then, the end of the giving tube and the end of catheter are aligned and the connection is made by forcing them

together. At this stage the outside of the plug may be manually wiped through the flexible wall so as to render it clean.

In the accompanying drawings:—

5 Fig. 1 is a side view of the coupling with the temporary enclosure made,

Fig. 2 is an end view on the arrow II,

10 Figs. 3, 4 and 5 show in longitudinal cross-section stages in the disconnection and plugging of the catheter end from the giving tube end and

Fig. 6 is a sketch of a complete peritoneal dialysis equipment.

Referring first to Fig. 6 there is shown a catheter 1 of which part 2 penetrates the abdominal wall and the peritoneal membrane. Its end exposed outside the abdomen is coupled for example by a Luer fitting to a long, flexible giving tube 3 on the other end of which is permanently welded a boss 4 with a handle 5 and projecting spike (not seen in this Figure) which 20 pierces a septum in the neck 6 or a bag 7 so as to be placed in fluid communication with the inside of that bag.

The catheter 1 has permanently at its end a boss 9 which is a rigid moulding. Over this boss 9 fits a 25 sleeve 10 which is part of a bellows 11 which is to form a flexible-walled temporary enclosure between the boss 9 and a boss 12 permanently secured to the end of a giving tube 3.

The bosses and bellows are preferably not of generally cylindrical conformation but are, as is best seen in Fig. 2, generally rectangular in end view so that there is one direction in which the flexible walls when pressed transversely of the axis of the catheter can be readily squeezed together, into contact with 30 each other if necessary.

The manner in which this enclosure is formed and used is seen in Figs. 3, 4 and 5.

Fig. 3 shows the enclosure as it is when a connection is made between the giving tube 3 opening into its boss 12 and the catheter 1 opening into its boss 9. 40 The giving tube boss has a male Luer projection 13 locking with and entering into a female Luer fitting 14 projecting from the catheter. Also on the boss 12 there is a peg 15 which acts as a temporary retainer for a plug 16 which also has a Luer taper and is adapted for a tight fit into the female fitting 14. The peg 15 enters into an internal recess 17 in the plug and forms a secure fit with it.

The bellows 11 is distorted during this fitting, with 50 the sleeve 10 however forming a secure and airtight sliding fit on the boss 9.

The internal surface of the bellows 11 preferably has a liquid absorbent layer 18 such as a layer of medical gauze which is preferably held there by having been moulded in situ during the formation of the bellows, for example a dip moulding process. This absorbent layer will preferably have been soaked before the first use of the coupling in a sterilising material such as Hibitane (Registered Trade Mark). 55

When it is desired to change the giving tube the user holds the two bosses 9 and 12 in his hands and draws them apart breaking the connection between the Luer fittings 13 and 14 (Fig. 4) but keeping the sleeve 10 on the boss 9.

65 The bellows is now flexed laterally in the opposite

direction to that seen in Fig. 3 so that the plug is aligned with the female fitting 14 and is forced into that fitting. A skirt 19 on the plug surrounds the outside of the fitting and helps to maintain that covered.

70 The fit of the plug 16 within the female fitting 14 is tighter than the fit of the peg 15 into it, so when the bosses 9 and 12 are again separated by the user the plug is left in situ, plugging the end of the catheter. Now the used giving tube may be withdrawn complete with its bellows 11, the end sleeve 10 sliding off the boss 9. Before a new giving tube is used, its end is immersed in sterilising medium which is soaked into the absorbing medium 18 within its bellows. The new connection is formed by sliding the sleeve 80 10 over the boss 9 forming a clean temporary enclosure between the bosses 9 and 12. The new connection does not have a plug 16 fitted on its peg. To form the connection, the male Luer 13 is preferably wiped by compression of the walls laterally upon it by the fingers of the user and then the peg 15 is brought into alignment with the end of the plug and fitted within the recess 17. To take the plug from the catheter the plug head must be gripped by the fingers of the user through the flexible wall. While so 90 gripping the bosses 9 and 12 are separated and the position is now again as seen in Fig. 4. The Luer fittings 13 and 14 are then aligned and the bosses pushed together so as to bring us to the position seen in Fig. 3. During this stage the external surface of the plug 16 can be wiped by manipulation of and pressure on the flexible wall of the temporary enclosure.

It can be seen that the plugging and unplugging operations and the connection and disconnection 100 operations have taken place in a clean environment defined by the temporary enclosure formed by the flexible wall of the bellows 11.

CLAIMS

1. Peritoneal dialysis equipment having a catheter and a giving tube to be removably connected together in which on one of the catheter and the giving tube a flexible wall is provided to form a temporary clean enclosure around the point of connection of the catheter and the giving tube. 105

2. Peritoneal dialysis equipment according to claim 1 in which the flexible wall is a tube permanently attached to a boss at the end of the giving tube and removably slidable over a boss at the end of the catheter. 110

3. Peritoneal dialysis equipment according to claim 1 or claim 2 in which there is provided a plug which fits removably onto the end of the catheter so as to temporarily seal it, and in which there is provided within the volume of the enclosure a peg on which the plug may sit when it is not fitted onto the end of the catheter. 120

4. Peritoneal dialysis equipment according to claim 3 in which the peg is integral with the end of the giving tube.

5. Peritoneal dialysis equipment according to any one of the preceding claims in which the flexible wall is of a bellows construction which is flexible in both the axial and transverse directions. 125

6. Peritoneal dialysis equipment according to any one of the preceding claims in which the inner 130

surface of the flexible wall is formed at least in part of a liquid absorbent material.

- 5 7. Peritoneal dialysis equipment according to claim 6 in which the absorbent material is a gauze firmly attached to the rest of the flexible wall by having been moulded in situ during the formation of the flexible wall.

- 10 8. Peritoneal dialysis equipment as herein described with reference to and as illustrated in the accompanying drawings.

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